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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/593,827	06/13/2000	Sherry X. Guo	LIFE-008	7505

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Bret Field
Bozicevic Field & Francis LLP
200 Middlefield Road
Suite 200
Menlo Park, CA 94025

EXAMINER

CHAUDHRY, MAHREEN F

ART UNIT PAPER NUMBER

1623

DATE MAILED: 03/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/593,827

Applicant(s)

GUO ET AL.

Examiner

Mahreen Chaudhry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

1. Acknowledgement is made of the amendment filed December 27, 2001. Claims 1, 11, 14, 19, 20 and 24 have been amended.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 1-23 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,972,294 issued to Smith et al. Smith et al. disclose a reagent test strip for use in the measurement of blood glucose. Smith et al. disclose that the reagent test strip comprises a polysulfone membrane, 10-(carboxymethylaminocarbonyl)-3,7-bis(dimethylamino) phenothiazine, glucose oxidase and horseradish peroxidase (Column 11, Lines 50+). Smith et al. further disclose that the test strip may be in an absorbance reading apparatus and that the timing of the measurement occurs automatically (Column 5, Lines 7-22; Column 3, Lines 58+). Smith et al. disclose that the change in reflectance is correlated with the glucose concentration in the sample (Column 7, Lines 17-19). Smith et al. exemplify polysulfones and nylons as appropriate porous matrix materials (Column 6, Lines 29-42).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. The applicability of Smith et al. to the instant invention has been discussed above. Smith et al. do not expressly disclose a kit comprising a reagent test strip, a means for obtaining a blood sample and an analyte standard. However, Smith et al. do teach that a sample of whole blood is placed on the surface of the test strip (Column 2, Lines 38-40). Although Smith et al. do not specifically disclose the means by which such a blood sample is obtained, such means would certainly have been obvious to one having ordinary skill in the art at the time of the invention. Furthermore, although Smith et al. do not specifically disclose a glucose standard, the use of such standards for comparison with test samples is conventional in the art and therefore, inclusion of a glucose standard, a means for obtaining a blood sample and a reagent test strip in a single package would have been obvious to one having ordinary skill in the art.

Response to Arguments

6. Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that the instant claims are distinguished from the teaching of Smith et al. in that the amended claims specifically recite that the test strip is storage stable for at least six months at

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temperatures ranging from -80°C to 60°C under humidity ranging from at least 0 to 20%.

Applicant further argues that since Smith et al. does not disclose the storage stability of the test strip, Smith et al. does not provide any suggestion or motivation for a kit comprising a test strip, a means for obtaining a blood sample and an analyte standard.

It is the examiner's position that since Smith et al. disclose a test strip having the same components as those recited in the instant claims, the disclosed test strip would necessarily have the same properties including storage stability. The instant claims recite a composition comprising a urea derivative dye on a positively charged porous matrix and dependent claims directed to the positively charged porous matrix as nylon and the dye as 10-(carboxymethylaminocarbonyl)-3,7-bis(dimethylamino)phenothiazine.

Smith et al. specifically disclose a test strip in which the dye may be 10-(carboxymethylaminocarbonyl)-3,7-bis(dimethylamino) phenothiazine and specifically exemplify polysulfones and nylons as appropriate porous matrix materials. Since the test strip disclosed by Smith et al. and the composition recited in the instant claims have the same components, the properties recited in the claims, regarding storage stability of the composition, are necessarily present since a chemical composition and its properties are inseparable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mahreen Chaudhry whose telephone number is (703) 605-1200. The examiner can normally be reached on Monday – Friday (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701 . The official fax phone number for the organization where this application is proceeding or assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

mc
March 4, 2002



RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200